

Tuesday
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Part IV

Environmental Protection Agency

Proposed Regulations for Registration of
Pesticides by States to Meet Special
Local Needs

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 162]

[OPP-3003A; FRL 1237-3]

Proposed Regulations for Registration of Pesticides by States to Meet Special Local Needs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes rules for the registration of pesticides by the States to meet special local needs, as authorized by sections 24(c) and 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended [FIFRA] (sections 22 and 23, Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136 *et seq.*). This proposed rule would clarify the scope of the authority granted to the States by the statute, describe registration procedures for EPA's exercise of its statutory power to disapprove certain State and registrations and to suspend State registration authority.

DATE: Comments must be received on or before September 6, 1979.

ADDRESSES: Interested persons are invited to participate in this proposed rulemaking by submitting written comments to the Document Control Officer, ATTN: Pesticides, Chemical Information Division, (TS-793), Office of Toxic Substances, Office of Pesticide Programs, EPA, Rm. E447, 401 M St., S.W., Washington, D.C. 20460. Comments should be filed in triplicate if possible, and should bear the identifying notation "OPP-30003A." All written comments filed will be available for public inspection from 8:30 a.m. to 4:00 p.m., Monday through Friday (excluding holidays), at the above address.

FOR FURTHER INFORMATION CONTACT: P. H. Gray Jr., Section 24(c) Working Group Leader, (TS-770-M), Office of Pesticide Programs, EPA, 401 St., S.W., Washington, D.C. 20460, 202-472-9400.

SUPPLEMENTARY INFORMATION: These rules are being proposed under the authority of sections 24(c) and 25(a)(1) of FIFRA and will be designated as §§ 162.150-162.155, Subpart B, Part 162, Title 40 of the Code of Federal Regulations. Subpart A of Part 162 establishes procedures and criteria for the registration of pesticides under section 3 of FIFRA.

The rules proposed as Subpart B are offered in lieu of the proposed rules establishing the interim section 24(c) program published on September 3, 1975

(40 FR 40538). When promulgated, these new rules will also replace the transitional section 24(c) policy statement signed on October 5, 1978, by the Deputy Assistant Administrator for Pesticide Programs.

Background

On September 30, 1978, the Federal Pesticide Act of 1978 (Pub. L. 95-396, 92 Stat. 819) amending the Federal Insecticide, Fungicide, and Rodenticide Act, (FIFRA) went into effect. The many changes made in FIFRA by Pub. L. 95-396 are described in another notice published in the Federal Register on January 19, 1979 (44 FR 4352).

Among the sections of FIFRA which were substantially modified is section 24(c) (section 2 of Pub. L. 95-396), which authorizes the States to register "additional uses of federally registered pesticides . . . to meet special local needs". To a significant degree, amendments to section 24(c) broaden State authority to issue such registrations, while they correspondingly limit EPA's authority over the State registration process. For example, the former requirement that States obtain certification from EPA prior to registering pesticides has been eliminated, and registration authority has been given directly to the States. Also, EPA's former broad authority to disapprove specific State registrations is now subject to certain express procedural and substantive restrictions. Nevertheless, EPA retains the ultimate responsibility for ensuring that the States act in accord with the purposes of FIFRA and for preventing unreasonable adverse effects on the environment. Implementation of this new relationship, therefore, requires close cooperation between EPA and the States.

This redistribution of authority necessitated the complete and immediate revision of the "Interim" program established by EPA in 1975 to implement the original version of section 24(c), including the proposed regulations accompanying the "Interim" program [40 FR 40438-40545 (September 3, 1975)]. Since regulations required to carry out the amended section could not be promulgated for some time, and since the need for States to register pesticides was continuous and substantial, EPA determined that the necessary revision must first appear in the form of a policy statement.

Accordingly, on October 25, 1978, after substantial public participation, the Deputy Assistant Administrator for Pesticide Programs, EPA, signed into effect a temporary transitional policy for implementing the amended section 24(c).

[See Attachment.] This policy was written to serve as a guide to the States, to registrants, and to other interested parties, until such time as regulations under section 24(c) could be promulgated.

Discussion of Major Provisions and Issues

Definitions

The definitions contained in FIFRA and in 40 CFR 162.3 of the rules for registration under Section 3 of FIFRA also apply to proposed § 162.151. Several definitions are provided for new terms, such as "similar composition" and "similar use pattern" which differ somewhat from the meaning given them in the transitional policy statement. "Similar composition" now refers to a State registered product which has the same active ingredients, and is in the same toxicity category, as the federally registered product to which it is compared. The term no longer requires that active ingredients be in the same percentages as the federally registered product, or that the formulation type be the same.

"Similar use pattern" continues to be interpreted broadly and is now defined simply as a pesticide use which is substantially similar to, and which does not require different precautionary labeling than, the federally registered uses to which it is compared. Changed use patterns, as defined in 40 CFR 162.3(k), are not considered similar use patterns. EPA wishes to point out that a change in precautionary labeling, incorporated by a State in supplemental labeling under section 24(c) in response to local conditions, rather than because the federal labeling standards require such a change, does not necessarily mean that the State registered use is not "similar" to a federally registered use.

Although EPA has responded to comments from State officials concerned about the above definitions, it should also be pointed out that these terms do not limit the scope of State registration authority. States have as much authority to issue registrations which are not similar to federal registration as they do to issue registrations which are similar. Rather, these terms primarily concern EPA's authority to disapprove State registrations.

In addition, EPA is proposing a definition of "special local need." This definition is included in response to comments received from State officials and other persons who feel that there must be some sort of guidance for States in order that the states may determine whether a special local need exists. On

the other hand, several persons commented that the States should have the responsibility to decide whether a given situation constitutes a special local need, and must have a substantial degree of discretion in order to do so effectively. Accordingly, EPA's proposed definition will meet this legitimate concern. The definition in § 162.151(j) requires that an actual pest problem exist in the State, which cannot be effectively controlled by an appropriate federally registered product. However, the definition clearly leaves the State free to decide whether such a problem actually exists, and whether any federally registered products are appropriate and available, based on information obtained. Such information may include expert opinion based on facts observed by a qualified expert employed or consulted by the State. However, a testimonial opinion given without explanation of its factual basis is not sufficient in itself to support a finding of a special local need.

The proposed definition of "federally registered," § 162.151(a), is slightly different from the meaning of that term as used during the Interim section 24(c) program. As now defined, the term includes only current registrations initially issued by the Administrator under section 3 of FIFRA, as amended, 7 U.S.C. 136a, or by the Administrator or the Secretary of Agriculture under section 4 of the FIFRA of 1947, 7 U.S.C. 135b.

Finally, the term "manufacturing-use product" is also defined in the proposed rule. This term merely refers to the use of technical grade products in the formulation of end use products, and is used in § 162.152(c) to help describe the scope of State registration authority.

State Registration Authority

Several persons who read the transitional policy statement commented that the statement did not clearly describe the types of registrations which States may issue under section 24(c)(1). EPA has considered at length these and other comments, as well as the language of, and Congressional intent behind, section 24(c)(1). EPA has concluded that the statutory language authorizing State registrations of "additional uses of Federally registered pesticides" clearly authorizes registration of additional uses of pesticide products currently registered by EPA under section 3 of FIFRA. On the other hand, there is some question as to whether section 24(c)(1) also authorizes State registration of new pesticide products. A strict interpretation of the statutory language

might indicate that States are not authorized to issue any registration for a product not currently registered by EPA. However, EPA believes that Congress did not intend to limit the States in this manner. Such an interpretation would prevent the States from issuing new product registrations which they were authorized to issue under the original section 24(c). This result would be inconsistent with Congress' general intent to broaden State registration authority under the amended section. In addition, the legislative history of the section 24(c) amendments contains several references to State registration of "pesticides" which indicate that Congress intended to give the States authority to register some new products.

Accordingly, proposed § 162.152(b)(2) indicates that States are authorized to register many types of new products, as under the Interim section 24(c) program. Proposed § 162.152(b)(2)(ii)(C) points out, however, that section 24(c)(1) only authorizes States to register products formulated with ingredients found in Federally registered products, i.e., products registered under section 24(c) cannot contain new chemicals.

Section 162.152(b)(2)(iii) clarifies that States are not authorized to register new technical grade products. This provision is necessitated by the language of section 24(c)(1) which limits State authority to registration of pesticides "formulated for distribution and use within that State * * *". That language means that products, or uses, registered by a State must be for end use within the State. In addition, if States were authorized to register technical grade materials, registrants could then easily use section 24(c) as a means to avoid the requirements of section 3(c)(1)(D) [data use compensation], thereby negating the purpose and intent of the latter section. Since FIFRA must be construed as whole, it is necessary to interpret section 24(c) in a manner consistent with section 3(c)(1)(D), and not in a manner which would upset the section 3(c)(1)(D) program. Therefore, technical grade materials, which are formulated solely for use in the manufacture of other products, are not covered by the statutory grant of authority.

It has also been suggested that section 24(c)(1) was intended to limit State authority to registration of products formulated only from federally registered technical grade materials. This suggestion would bar State registrants from producing technical grade materials for their own use in manufacturing State registered end use products, unless they had first obtained a Federal registration for the technical

grade product. This interpretation would be consistent with the purpose and intent of section 3(c)(2)(D), and with EPA's policy of preventing contamination of end use products by checking technical grade materials for impurities. EPA encourages the public to comment on this issue and will respond to such comments when the final section 24(c) regulations are published.

Proposed § 162.152(b) also clarifies the prohibition in section 24(c)(1) against State registrations involving products for which registration of some uses has been denied, disapproved, or cancelled by the administrator. EPA interprets this prohibition as extending implicitly to cases where Federal registration has been suspended by EPA, and as applying equally to registrations of both new products and amendments to Federal registrations. EPA also believes that the statute authorizes registration of any use of a product for which registration has not been specifically denied, disapproved, suspended, or cancelled. However, to ensure close cooperation by the States and EPA in carrying out their joint duty to prevent the registration of a use of a product which could cause an imminent hazard to man or the environment, proposed § 162.152(b) requires States to consult with EPA prior to issuing registrations for some uses of products subject to partial denial, disapproval, suspension, or cancellation.

On this same topic, it has been suggested that the prohibition or limitations on State registration involving cancelled Federal registrations should expressly exclude voluntary cancellations by the registrant, unless the voluntary cancellation occurs subsequent to an EPA notice of intent to cancel. EPA also encourages public comment on this important issue.

Paragraph (a) in § 162.152 lists the conditions which section 24(c) expressly requires each State registration to meet in order for it to be considered valid under FIFRA. These include the conditions that a special local need for the registration exist; that clearances under the Federal Food, Drug, and Cosmetic Act [FFDCA] have been granted, if the pesticide is used on food or feed; and that registration for use of the product has not been denied, disapproved, or cancelled; and that the State registration is otherwise consistent with FIFRA. Clearances or tolerances for residues on food or feed under FFDCA must have been granted for all active and inert ingredients in the product, as well as all metabolites and by-products created by the product.

In addition, it should be noted that tolerances under the FFDCA are based on data from specific use patterns which are described in the products' labeling. When any of the usage parameters (e.g., dosage, frequency or timing of application, preharvest intervals) is changed, the level of the resulting residues may also change. In some cases, these changes could result in residues exceeding the tolerance level established for that pesticide. In such cases, the registration would be considered invalid under § 162.152 of the proposed rule, and, in addition, any contaminated food or feed would be subject to seizure and destruction under section 402(a)(2) of the FFDCA. Therefore, when a State is considering registration of a pesticide for a use different from any use of that pesticide for which a tolerance has been established, the State should evaluate residue data for the new use pattern. If the data evaluated indicates above-tolerance residues would result, then the registration should not be issued. If it is nonetheless, it will be considered invalid by EPA under FIFRA.

Proposed § 162.152(c) discusses the effect which a State registration has under FIFRA. It points out that valid State registrations are equivalent to registrations issued by EPA for all purposes under FIFRA. For example, registrations under section 24(c) are subject to section 6 [suspension and cancellation] and 13 [Stop-sale, use, removal, and seizure orders] of FIFRA. On the other hand, section 24(c) registrations are not subject to those provisions of section 3 of FIFRA which apply only to applications for registration under section 3 [e.g., exclusive data use and data compensation]. This is because the language in section 24(c)(1) equating valid State registrations to Federal registrations clearly does not apply to mere applications for State registration, but only to registrations actually issued. Therefore, only those provisions of FIFRA which come into play after issuance of a Federal registration will be applicable to registrations under section 24(c). In addition, the data use and compensation provisions of section 3(c)(1)(D), by their own terms, apply only to applicants for registration by EPA.

Finally, paragraph (c) makes it clear that States are free to impose time limits on, or revoke or suspend, parallel State law registrations issued by them, as permitted by State law. Such actions will, for all practical purposes, effectively limit or terminate the registration within that State, even

though they do not automatically affect the technical validity of the FIFRA registration for purposes of Federal law. However, if the State action is based on health, safety, environmental, or other substantial concerns, EPA will, in consultation with the State, take appropriate action under FIFRA. Such action may include suspension or cancellation of the registration under section 6 of FIFRA.

State Registration Procedures

Proposed § 162.153 describes registration procedures which States must follow in issuing registrations under section 24(c). EPA believes that the procedures described in § 162.153 represent the minimal requirements which, as experience under the Interim program has shown, are necessary to enable States to prevent the registration of products, and uses thereof, which would be harmful to man or the environment. Such procedures must be followed in order for EPA and the States to be able to work in an informed and effective manner as partners in the regulation of pesticide use.

Proposed § 162.153(a) outlines the basic information which must accompany every application for registration under section 24(c). This includes a copy of all draft labeling for State review. However, as requested by several commenters, and in accordance with practices followed under the Interim programs, labeling for proposed amendments to Federal registrations may be satisfied by submission of the labeling from the federally registered product, together with supplemental labeling meeting the criteria of proposed § 162.153(e)(3).

In keeping with Congress' intent to broaden State responsibility under section 24(c), proposed § 162.153(b) gives States discretion to decide whether a special local need (as defined in § 162.151) exists for a proposed registration. Section 162.153(b) does, however, describe two situations which a State may consider as not involving a special local need, based on language contained in the December 1978 Report of the State-Federal Issues Research and Evaluation Group [SFIREG] Working Committee on Registration and Classification. In any case, however, States must take special care to prevent section 24(c) from being used by registrants to circumvent the requirements of section 3.

Proposed § 162.153(c) would require States to conduct hazard reviews before issuing registrations for certain products or uses in situations which might involve the creation of unreasonable

adverse effects on the environment, including registration of products with compositions or uses never registered by EPA. Both § 162.153(c) and § 162.153(d) [efficacy reviews] require the States to base their determinations on data and criteria equivalent to those used by EPA in making hazard and efficacy decisions under section 3 of FIFRA. To this end, § 162.153 (c) and (d) [incorporate by reference provisions] of 40 CFR Parts 162 and 163, regulations and guidelines issued under section 3. EPA notes that additional, more specific, information on hazard and efficacy reviews will be contained in new guidelines to be added to Part 163. If those guidelines are promulgated before this rule, the references in § 162.153 (c) and (d) will be modified accordingly.

Proposed § 162.153(d) differs from the Interim proposed rules of 1975 in that it would require States to determine the efficacy of a product, or use thereof, only when it is intended for registration for a use which could adversely affect the public health should the product not prove efficacious. This includes applications for each product bearing a claim to control organisms that threaten human health, either directly or through transmittal of diseases, such as: antimicrobial agents for control of hazardous microorganisms infectious to man; formulations for control of vertebrates that may transmit disease to man; and products intended to control mosquitos, cockroaches, fleas, ticks, lice, biting flies, houseflies, poisonous spiders, fire ants, hornets, wasps, bedbugs, scorpions, centipedes, or aflatoxin-producing fungi. This more limited requirement is consistent with EPA's current policy for dealing with new registrations under section 3 of FIFRA. However, EPA realizes that many States may wish to, or are required to, make efficacy determinations for all applications. EPA encourages such States to do so, especially since section 3(c)(5) of FIFRA also implicitly encourages such a procedure by establishing a presumption that the Administrator will waive efficacy data under section 3(c) whenever a State has found a product to be efficacious.

Proposed § 162.153(e) specifies in more detail than the proposed 1975 rules what the labeling for section 24(c) registrations must contain. In general, the labeling must meet the requirements of federally approved labeling under 40 CFR 162.10. Information to be contained in supplemental labeling for amendments to federal registrations represents the minimum information needed to ensure safe use of the product

should the supplemental labeling be inadvertently separated from the original federally approved labeling. [EPA emphasizes, however, that both supplemental and original labeling for such products *must*, under section 12 of FIFRA, accompany the product at the time of use.] In addition, the section makes allowances for States exercising their power to impose additional restrictions on pesticide use, by permitting the addition of new precautions and restrictions on supplemental labeling for any State registered product.

Proposed § 162.153(g) specifies situations in which a State must classify a product or use as a restricted use pesticide. In general, this must be done when the registration is for a product similar to a federally restricted use pesticide, or for an additional use of a federally restricted use pesticide. Of course, States have the discretion to restrict, or not to restrict, any product or use not specifically required to be restricted by this rule. However, since valid registrations issued under section 24(c) are considered "federal registrations" under FIFRA, any action by EPA to restrict a pesticide use will automatically apply to all valid registrations previously issued under section 24(c) for that pesticide [see 43 FR 5782]. In such a case, EPA will have the responsibility for notifying the affected section 24(c) registrants of the classification and for ensuring that the labeling of the pesticides reflects the restriction [see 40 CFR 162.11(d) and 162.30 (c)(3) and (d)]. Of course, in all such cases, EPA will communicate directly with affected States in order that the States may take any necessary action under State law consistent with the EPA decision.

Consistent with previous agreements between EPA and representatives of the States, § 162.153(h) requires states to notify EPA of each registration or amendment or revocation thereof. In addition, under proposed § 162.153(h)(4), EPA may request States to submit data used by the State in making a determination under § 162.153(c) that a registration will not cause an imminent hazard in cases involving new products with new compositions, or new uses for a federally registered product subject to denial, disapproval, suspension, or cancellation by EPA, or subject to a notice of intent to deny, disapprove, suspend, or cancel. Such information will be needed by EPA to ensure that the registration does not involve an imminent hazard or a violation of the Federal Food, Drug, and Cosmetic Act. However, it has also been suggested

that § 162.153(h)(2) should be expanded to allow EPA to request hazard data from the States in every case in which a State is required by § 162.153(c) to make a hazard determination. In effect, this would mean expanding § 162.153(h)(2) to include cases where the State has registered a new use of a product not similar to any federally registered use of that same product or of a product with a similar composition. In some such cases, hazard data might be essential to EPA in determining whether an imminent hazard exists. EPA invites the public to comment on this suggestion.

Section § 162.153(i) requires the Administrator to publish in the Federal Register periodic summaries of State registrations. This requirement is inserted at the request of State officials who believe that such a procedure is needed to enable the States to keep abreast of section 24(c) actions across the nation. EPA acknowledges this need and encourages States to take advantage of this procedure, when it is implemented, so that States may observe whether a particular registration has been issued by other States on an interregional or nationwide basis.

Disapproval of State Registrations

Proposed § 162.154 specifies grounds and procedures for the exercise of EPA's authority to disapprove individual State registrations issued in violation of FIFRA or of Subpart B. As pointed out earlier, the scope of EPA's authority generally depends on whether the State registration involves a product with composition and use pattern similar to a federal registered product. If the State registered product is a "similar product", EPA cannot disapprove the registration unless it would create an imminent hazard or violate the Federal Food, Drug, and Cosmetic Act requirements for use on food or feed. If the State registered product is not similar, in either composition or use pattern, to the federally registered product, then EPA may disapprove the State registration on any reasonable grounds.

Disapproval of State registrations is, of course, not the same as refusal, suspension, or cancellation of registrations under sections 3 and 6 of FIFRA. Therefore, holders of disapproved State registrations are not subject to the indemnity provisions of section 15 of FIFRA.

Procedures for disapproval include a requirement for prior written notification to, and consultation with, the registering State in all cases except those involving an imminent hazard or a violation of the Federal Food, Drug, and

Cosmetic Act. In those two situations, the administrator is authorized by section 24(c) to disapprove a registration immediately. However, in such cases, EPA intends to follow the procedures for prior written notification and consultation with the State whenever possible. In addition, even in those few cases where such procedure must be omitted because of the imminence of potential harm, EPA will give the registering state informal notice of the disapproval prior to publication of the formal notice of disapproval. Furthermore, in such a case the proposed rule provides for subsequent consultation, on request, with the State.

Other procedures contained in proposed § 162.154 also offer the States a full measure of participation in the disapproval process. Except in those cases where immediate disapproval is authorized and appropriate, EPA will provide the States with a prior notice of *intent* to disapprove, specifying grounds therefor, and inviting the State to consult with EPA officials. Similarly, before rescinding a previously issued disapproval notice, EPA will consult with the affected State as to the advisability of such an action. EPA hopes that the States will take full advantage of these opportunities to cooperate with EPA in the exercise of this important function.

Finally, proposed § 162.154(c) provides that all procedures for disapproving a State registration, or amendment thereto, must be completed within 90 days of the registration action (or within 90 days of EPA's receipt of notification of the State action if such notice is delayed beyond the ten days allowed by § 162.153(h)), except in those cases involving an imminent hazard or a violation of the FFDCA. EPA interprets the 90 day limitation imposed by section 24(c) as not applying to these two types of disapprovals since the apparent purpose of the 90 day period is to allow EPA enough time to comply with procedural requirements which are not applicable to such disapprovals.

Suspension of State Authority

Proposed § 162.155 specifies grounds and procedures for suspension of State registration authority. Suspension may be imposed under section 24(c)(4) if a State lacks "adequate controls", or fails to exercise adequate controls, over its registration program. The statute directs EPA to specify by regulation what it considers to be "adequate controls". Accordingly, § 162.155(b) describes what EPA considers to be the minimal personnel resources, procedures, and legal authorities necessary for a State to

implement a registration program which "assures that State registration[s] . . . will be in accord with the purposes of" FIFRA, but which accords the State maximum flexibility in designing their programs.

Section 162.155(b) also provides for a flexible response by EPA should a State prove unable to maintain a completely adequate program. This paragraph will permit the Administrator to suspend that part of a State's authority for which it lacks adequate controls, while leaving intact those parts of the State's authority for which it has, and exercises, control.

Finally, the procedures for suspension, like those for disapproval of registrations, have been drafted to provide for maximum cooperation between EPA and the States. Prior to deciding whether to suspend any State's authority, the Administrator will send written notification of his intent to that State, specifying the grounds for concern, and inviting the State to consult with EPA officials. Of course, before such formal procedures are begun, the Administrator will seek resolution of any apparent problems through informal, private, negotiations with the State. Only if all such formal and informal proceedings do not produce a satisfactory solution to such deficiencies will the Administrator finally suspend a State's authority.

Provisions Not Applicable to States

Section 162.156 contains several requirements derived directly from FIFRA which apply to producers, registrants, and users of State registered pesticides. Paragraph (a) points out that State registrations not issued in accordance with section 24(c) and proposed § 162.152 (a) and (b) are unauthorized and invalid for all purposes under FIFRA. In such a case, EPA may notify the State that the registration is not valid, and may specify the reason(s) why. However, such notification is not equivalent to a notice of disapproval. In order to implement the Administrator's authority to *disapprove* a registration under section 24(c), positive action, including notice to the State, is required. On the other hand, a State registration which does not satisfy the basic conditions imposed by section 24(c), as listed in proposed § 162.152 (a) and (b), is automatically invalid, even without any affirmative action being taken by EPA. Therefore, a notice of invalidity may be issued by EPA at any time and in any form deemed reasonable by the Administrator.

Distribution of a pesticide product under an invalid State registration is a

violation of section 12 of FIFRA. In addition, distribution and use of a pesticide under a valid State registration must be made in accordance with the provisions of section 12. EPA wishes to point out that a pesticide which has been issued a valid registration by one State, may be shipped to that State from any other State without violating section 12(a)(1)(A).

Paragraph (b) and (c) of § 162.156 point out that sections 7 (establishment registration) and 8 (recordkeeping) of FIFRA, and rules thereunder, are applicable to *all* pesticide producers, including producers of State registered pesticide products.

Miscellaneous

Several comments on the transitional policy statement indicate that some confusion exists as to the status of "third party" and "me-too" registrants under the transitional policy. EPA believes that the current proposed rule is clear, but wishes to emphasize that "third party" registration (registration in a State for a new use of a federally registered product by a person other than the federal registrant), if permitted by State law, is possible under this rule. In addition, it should be noted that such a registration is not a new product registration as long as the formula and formulation type, the package, and the formulator, of the State registered product are the same as those for the federally registered product. However, EPA must reject one commenter's suggestion that the rules impose "full liability" for use of the product on "third party" registrants who do not obtain consent to the State registration from the federal registrant. Such matters are not within the scope of this rule, or within EPA's jurisdiction, but are, rather, matters to be resolved under the State law or between the affected parties.

Similarly, "me-too" registrations (registration in a State by a new formulator of a product which is already registered by another formulator), if authorized by State law, are also permitted under this rule, if the State determines that a special local need for the registration exists.

EPA must also reject a suggestion that these rules require "me-too" and "third party" registrants to notify the prior registrant(s) of the new registration. Such a requirement is not necessary to the effective implementation of section 24(c), and is an issue which should be settled under State law, or as a business matter. However, EPA encourages "third party" registrants to provide such notice, and to seek consent where

appropriate, in order that State registrations may be issued in an informed, responsible fashion [see EPA P.R. Notice 77-3 of 5/17/77].

Regulatory Analysis

EPA has determined that this rule does not require a Regulatory Analysis under Executive Order 12044. A screening study to this effect is available for review.

Statutory Review

The U.S. Department of Agriculture has reviewed the proposed regulation in accordance with section 25(a) of FIFRA and concurs without comments in its publication in the Federal Register.

The regulation was also submitted for scientific review and comment to the FIFRA Scientific Advisory Panel (SAP) in accordance with section 25(d) of FIFRA. In a report dated May 11 to the EPA Deputy Assistant Administrator for Pesticide Programs, the SAP concurred without comment in the proposed regulation.

Regulatory Review

Section 2(d)(8) of Executive Order 12044 requires that a plan for evaluating the regulation after its issuance be developed. The Agency's plan for evaluation of this rule calls for an analysis by EPA of the regulation and its effect on State regulatory agencies and registrants, in cooperation with the State-FIFRA Issues Research and Evaluation Group. This evaluation will be performed within five years from the date of promulgation of this rule, and a determination will then be made, based upon such evaluation, as to whether modification of the rule is necessary.

Dated: July 31, 1979.

Douglas M. Costle,
Administrator.

It is proposed to amend 40 CFR Part 162 by establishing Subpart B, to read as follows:

Subpart B—Regulations Pertaining to State Registration of Pesticides to Meet Special Local Needs

- Sec.
- 162.150 General.
- 162.151 Definitions.
- 162.152 State registration authority.
- 162.153 State registration procedures.
- 162.154 Disapproval of State registrations.
- 162.155 Suspension of State registration authority.
- 162.156 General requirements.

Authority.—Sections 24(c) and 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (sections 22 and 23, Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136 *et seq.*)

§ 162.150 General.

(a) *Scope.* This subpart sets forth regulations governing the registration by any State of pesticide products, or uses thereof, formulated for distribution and use within the State to meet special local needs. It also sets forth regulations governing the exercise by the Administrator of the power to disapprove specific State registrations and to suspend a State's registration authority. Unless otherwise indicated, any reference herein to registrations issued by a State includes amendments of registrations issued by States.

(b) *Applicability.* This subpart applies only to State registration authority granted by section 24(c) of FIFRA. It does not apply to any authority granted or procedures established by State law with respect to registration, licensing, or approval required for use within the State of federally registered pesticide products. In addition, this subpart does not apply to products or uses registered by a State prior to August 4, 1975, which were not subsequently registered by the State under section 24(c), or by EPA, and which have continued in intrastate commerce in accordance with 40 CFR 162.17.

§ 162.151 Definitions.

Unless otherwise indicated, terms used in the subpart have the meanings set forth in the Act and in subpart A of this part. In addition, as used in this subpart, the following terms have the meanings set forth below:

(a) "Federally registered" means currently registered after having been registered under the Federal Insecticide, Fungicide and Rodenticide Act by the Secretary of Agriculture, or by the Administrator.

(b) "Manufacturing-use product", means any pesticide product other than a product to be labeled with directions for end use. This term includes any product intended for use as a pesticide after re-formulation or repackaging.

(c) "New product" means a pesticide product which is not a federally registered product.

(d) "Pest problem" means (1) a pest infestation and its consequences, or (2) any condition requiring the use of plant regulators, defoliants, or desiccants.

(e) "Product," or "pesticide product" means a pesticide offered for distribution and use, and includes any labeled container and any supplemental labeling.

(f) "Similar composition" refers to a pesticide product which contains only the same active ingredient(s), or combination of active ingredients, and which has the same category of toxicity,

as a federally registered pesticide product.

(g) "Similar product" means a pesticide product which, when compared to a federally registered product, has a similar composition and a similar use pattern.

(h) "Similar use pattern" refers to a use of a pesticide product which, when compared to a federally registered use of a product with a similar composition, does not require a change in precautionary labeling under § 162.10(h), and which is substantially the same as the federally registered use. Registrations involving changed use patterns are not included in this term.

(i) "Special local need" means an existing or imminent pest problem within a State for which the State lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available.

(j) "State," or "State lead agency," as used in this subpart means the State agency designated by State law or other authority to be responsible for registering pesticides to meet special local needs.

§ 162.152. State registration authority.

(a) *Statutory limitations.* In accordance with section 24(c) of the Act, each State is authorized to register a new product for any use, or an additional use of a federally registered pesticide product, if the following conditions exist:

(1) There is a special local need for the use within the state;

(2) The use is covered by necessary tolerances, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346 et seq.), if the use is a food or feed use;

(3) Registration for the same use has not previously been denied, disapproved, suspended or cancelled by the Administrator, because of health or environmental concerns about an ingredient contained in the pesticide product, unless such denial, disapproval, or suspension or cancellation has been superceded by subsequent action of the Administrator;

(4) The registration would be in accord with the purposes of FIFRA.

(b) *Types of registrations.* (1) *Amendments to Federal registrations.* (i) Subject to the provisions of paragraph (a) and paragraph (b)(1)(ii) of this section, States may register any new use of a federally registered pesticide product.

(ii) States may register any use of a federally registered product for which

registration of other uses of the product was denied, disapproved, suspended, or cancelled by the Administrator, provided that the State may register a use not considered by the Administrator in reaching such a determination only after the State consults with appropriate EPA personnel.

(2) *New products.* (i) Subject to the provisions of paragraph (a) and paragraphs (b)(2)(ii)-(iii) of this section, States may issue registrations to meet special local needs for the following types of new products:

(A) A product which is identical in composition to a federally registered product, but which has differences in packaging, in formulation type, or in the identity of the formulator;

(B) A product which contains the same active and inert ingredients as a federally registered product, but in a different percentage;

(C) A product containing a new combination of active, or active and inert, ingredients, provided that States may not register a new product which contains any active or inert ingredient not found in a federally registered product.

(ii) States may not register a new manufacturing-use product.

(iii) States may register any use of a new product containing an ingredient described in paragraph (a)(3) of this section, if the new product registration is for a formulation or a use not included in the denial, disapproval, suspension, or cancellation. However, a formulation or use of the new product which was not considered by the Administrator during such proceedings may be registered by a State only after the State consults with appropriate EPA personnel regarding the registration application.

(c) *Effect of State registration.* (1) A State registration issued under FIFRA section 24(c) which meets the conditions described in paragraph (a) and (b) of this section, and which is not disapproved by the Administrator under § 162.154, shall be considered a federal registration, but shall authorize distribution and use only within that State. Accordingly, such registrations are subject to all provisions of FIFRA which apply to currently registered products, including cancellation, renewal, suspension, and other provisions of sections 6 and 13 of FIFRA.

(2) A State may require, as a condition of distribution or use of a pesticide product within the State, that the pesticide product be registered under State law as well as under FIFRA. Neither FIFRA section 24(c) nor this regulation affects a State's right under

its own law to revoke, suspend, cancel, or otherwise affect such a registration issued under State law. However, the federal registration, whether issued under FIFRA sections 3 or 24(c) would not be affected by such a State action.

§ 162.153. State registration procedures.

(a) *Application for registration.* States shall require all applicants for registration to submit the following information:

(1) Name and address of the applicant and any other person whose name will appear on the labeling or in the directions for use;

(2) The name of the pesticide product, and, if the application is for an amendment to a federally registered product, the EPA registration number of that product;

(3) A copy of proposed labeling, including all claims made for the product as well as directions for its use to meet the special local need, consisting of:

(i) A copy of the complete proposed labeling for a new product; or,

(ii) A copy of proposed supplemental labeling for registration of an additional use of a federally registered product, together with a copy of the labeling for the federally registered product;

(4) The complete formula of the product, if the application is for a new product registration;

(5) Any other information which is required to be reviewed prior to registration under this section.

(b) *Special local need determination.* In reviewing any application for registration, the State shall determine whether there is a special local need for the registration. Situations which a State may consider as not involving a special local need may include, but are not limited to, use to control a pest problem present on a nationwide basis, and use of a pesticide product registered by other States on an interregional or nationwide basis.

(c) *Unreasonable adverse effects determinations.* (1) Prior to issuing a registration in the following cases, the State shall determine that use of the product for which registration is sought would not cause unreasonable adverse effects on man or the environment, when used in accordance with labeling directions or widespread and commonly recognized practices:

(i) For use of a product which has a composition not similar to any federally registered product;

(ii) For use of a product involving a use pattern not similar to any federally registered use of the same product or of a product with a similar composition; or

(iii) For use of a product for which other uses of the same product, or of a product with a similar composition, have had federal registration denied, disapproved, suspended or cancelled by the Administrator.

(2) Determinations required by paragraph (c)(1) of this section shall be based on data and criteria consistent with those sections of subpart A of this part, and of Part 163, applicable to the type of product or use under consideration. Such determinations may also involve consideration of the effect of the anticipated classification of the product or use under § 162.153(h).

(d) *Efficacy determination.* Prior to registration of a product, or use thereof, for public health purposes, which could result in substantial harm to the public health if the product does not perform its intended function, the State shall determine that the product warrants the claims made for it in the registration application. Such determinations shall be based on criteria specified in applicable sections of subpart A and of part 163 and on any additional criteria established by the State.

(e) *Labeling requirements.* (1) Prior to issuing any registration, the State shall review the proposed labeling submitted with the application to determine compliance with this paragraph. In addition, the State shall review a copy of the final printed labeling as soon as practicable after a registration is issued in order to verify compliance with this paragraph.

(2) A new product registered by a State must be accompanied, at the time of use, by labeling meeting all applicable criteria of § 162.10 of subpart A. New product labeling must also contain:

(i) A statement identifying the State where registration is to be valid; and

(ii) The special local need number assigned by the State.

(3) For a registration of an additional use of a federally registered product, labeling from the federally registered product must be accompanied at the time of use by supplemental labeling which contains:

(i) A statement identifying the State where registration is valid;

(ii) Direction for use to meet the special local need which satisfy the criteria of § 162.10(i) of subpart A;

(iii) The trade name of the product;

(iv) The name and address of the section 24(c) registrant;

(v) The EPA registration number of the federally registered product;

(vi) The special local need number assigned by the State;

(vii) A statement requiring a person using the product to comply with all applicable directions, restrictions, and precautions found in the labeling of the federally registered product; and,

(viii) A statement prohibiting use of the product in a manner inconsistent with federal, and accompanying supplemental, labeling.

(4) If a State classifies for restricted use a product or use registered by the State, which is not required to be so classified by paragraph (g) of this section, then the State may require supplemental labeling for the product or use containing additional appropriate precautions, and a statement that the product or use is for restricted use within that State.

(f) *Packaging and coloration standards.* All products registered by a State must meet all appropriate packaging standards prescribed by the Administrator under section 25(c)(3) of FIFRA, as well as all appropriate standards for coloration, or discoloration, established by regulation under section 25(c)(4) of FIFRA, including the standards contained in § 162.13 of subpart A. Prior to issuing any registration, the State shall determine that the product will conform to these requirements.

(g) *Classification.* (1) As part of the registration of any product or use, the State shall classify the product or use consistently with section 3(d) of FIFRA and any regulations thereunder.

(2) A product or use thereof registered by a State must be classified by the State for restricted use if—

(i) The product is identical or similar in composition to a federally registered product;

(A) For which all uses have been classified as restricted by the Administrator; or

(B) For which a use similar to the State registered use has been classified as a restricted use by the Administrator; or

(ii) The State registered product or use meets the criteria for classification as a restricted use pesticide under the applicable provisions of § 162.11(c)(1)–(4) of subpart A.

(h) *Notification and submission of data.* (1) Within ten working days from the date a State issues, amends, or revokes a registration, the State shall notify EPA, in writing, of such an action. Notification of State registrations, or amendments thereto, shall include the effective date of the registration or amendment, a confidential statement of the formula of any new product, and a copy of the draft labeling reviewed and approved by the State, provided that

labeling previously approved by the Administrator as part of a federal registration need not be submitted.

(2) Notification of State registrations or amendments shall be supplemented by sending to EPA a copy of the final printed labeling approved by the State within 45 days after the effective date of the registration or amendment.

(3) Notification of revocation of registration by a State shall indicate the effective date of revocation, and shall state the reasons for revocation.

(4) Within 15 working days of receipt of a request from EPA, a State shall submit any data used by the State to determine that unreasonable adverse effects will not be caused by a registration of:

(i) A product with a composition not similar to any federally registered product; or

(ii) An additional use of a federally registered product, or a use of a product with a composition similar to that of a federally registered product, if registration of other uses of the federally registered product has been denied, suspended, or cancelled by the Administrator, or is subject to a notice of intent to deny, suspend or cancel registration because of health, safety, or environmental concerns.

(i) *Federal Register publication.* The Administrator shall publish in the Federal Register, on a regular basis, a summary of all State registrations made under section 24(c) during a previous reporting period established by the Administrator. For each product or use registered, the notice shall indicate the name of the product; the name of the registrant; the registered use(s) of the product; the effective date of the State registration; and, if the registration is for an additional use of a federally registered product, the notice shall indicate whether the State registration involves a changed use pattern.

§ 162.154 Disapproval of State registrations.

(a) *General disapprovals.* (1) Except as provided in paragraph (b) of this section, the Administrator may disapprove, on any reasonable grounds, any State registration which, when compared to a federally registered product, does not have both a similar composition and a similar use pattern; provided that the Administrator may not disapprove such a registration solely because of lack of essentiality. Grounds for disapproval of State registrations not involving similar products may include, but are not limited to:

(i) Probable creation of unreasonable adverse effects on man or the environment by the registered use;

(ii) Refusal of the registering State to submit information supporting the registration as required by § 162.153(h);

(iii) Failure of information submitted by the State to support the State's decision to issue the registration under standards established by § 162.153.

(2) Prior to disapproval of any State registration under this paragraph, the Administrator shall notify the registering State, in writing, of the Administrator's intent to disapprove, and of the reasons for disapproval. The notice of intent will provide a reasonable time, not less than ten days from the date the notice is received by the State, for the State to respond, and will invite the State to consult with the Administrator or his designee. If the grounds for disapproval are based on actions or omissions by the State, the notice will, if possible, also provide the State with a reasonable amount of time in which to take corrective action, not to exceed the time allowed for disapproval under paragraph (c) of this section.

(3) The registering State may, within ten days of its receipt of a notice of intent to disapprove, request that the Administrator, or his designee, consult with appropriate State officials prior to the Administrator's final decision on disapproval. The Administrator will consider any relevant information presented at such a consultation, or in any other timely and appropriate fashion, in deciding whether to withdraw the notice of intent to disapprove.

(b) *Special disapprovals.* (1) The Administrator may disapprove any State registration, including a registration for a similar product, at any time, if the Administrator determines that use of the product under the State registration:

(i) Would constitute an imminent hazard; or

(ii) May result in a residue on food or feed not covered by a tolerance, exemption, or other clearance under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a *et seq.*).

(2) If the Administrator disapproves a registration under this paragraph, the administrator shall provide the registering State with written notification of disapproval, in accordance with paragraph (c) of this section, as soon thereafter as practicable. Such notification will specify the grounds for disapproval and invite the State to comment.

(3) If requested by the State within ten days of its receipt of the notice of disapproval under this paragraph, the

Administrator, or his designee, will consult with appropriate State officials. The administrator may consider any information presented at such a consultation, or in any other appropriate fashion, in determining whether the disapproval should be rescinded.

(c) Except as provided in paragraph (b)(1) of this section, the Administrator will make a final decision on disapproval of a State registration, and provide written notification to the State within 90 days of the effective date of the registration; provided that, if the State does not notify the agency of the registration within ten days of its effective date, then the Administrator will make a final decision on disapproval within 90 days of the date on which EPA receives notification of the State registration. The notice of disapproval will specify a date on which disapproval becomes effective, which shall not be later than 90 days from the effective date of the State registration or, if the State does not notify EPA of the registration within ten days, 90 days from the date the Agency receives notification of the State registration, whichever comes later. The notice of disapproval may also, when appropriate, give instructions for disposal of the pesticide. Each such notice of disapproval will be published in the Federal Register.

(d) *Effect of disapproval.* If a registration issued by a State is disapproved by the Administrator, that registration will not be valid for any purposes under FIFRA, as of the date disapproval becomes effective. Accordingly, distribution of sale of a pesticide, in either interstate or intrastate commerce, for purposes covered by the disapproved State registration will be a violation of section 12(a)(1) of FIFRA.

(e) *Rescission of disapproval.* If the Administrator determines, after consultation with the State lead agency, that a registration, previously issued by the State and disapproved by the Administrator, should be recognized as valid under section 24(c) of FIFRA, then the Administrator shall rescind the disapproval. The Administrator shall send written notification of the rescission to the State. In addition, notice of any rescission of disapproval will be published in the Federal Register.

(f) *Notification of registrants.* Any State which issues a registration subject to disapproval, or to a notice of intent to disapprove, shall be responsible for notifying the affected registrant of any rescission of disapproval by the Administrator.

§ 162.155 Suspension of State registration authority.

(a) *General.* (1) If the Administrator finds that a State is not capable of exercising, or has failed to exercise, adequate control over its registration program, so that the State cannot assure that registrations issued by it will be in accord with the purposes of FIFRA, then the Administrator may suspend the State's registration authority.

Registrations issued by the State after suspension of its authority will not be considered valid under FIFRA.

Registrations issued by the State prior to suspension will not be affected by the suspension.

(2) The Administrator may suspend all or any part of a State's registration authority as may be appropriate under the circumstances.

(b) *Grounds for suspension.* (1) The Administrator may suspend a State's registration authority because of lack of adequate controls, including, but not limited to, lack of any of the following:

(i) Access to appropriate scientific and technical personnel to review data and make determinations as required by § 162.153;

(ii) Registration procedures satisfying § 162.153;

(iii) Complete and accurate records of State registrations; and

(iv) Adequate legal authority—

(A) To deny, suspend, revoke, or amend a State registration when the registration is not in compliance with FIFRA, this Subpart, or State law, or when necessary to prevent unreasonable adverse effects on the environment;

(B) To enter, at reasonable times, by consent, warrant, or other legal means, any establishment where pesticides are produced or held for distribution or sale, to inspect, sample, and observe whether pesticides are being produced, and distributed in compliance with FIFRA, this Subpart, State law, and the terms of any State registration.

(2) The Administrator may suspend all or any part of a State's registration authority if the State fails to exercise the controls specified in paragraph (b)(1) of this section, or if the State refuses to correct within a reasonable time any other deficiencies in its regulatory program specified by the Administrator in a notice of intent to suspend.

(c) *Procedures for suspension.* (1) Prior to suspending the registration authority of any State, the Administrator will notify the State lead agency, in writing, of the Administrator's intent to suspend, and of the specific grounds for suspension. The notice of intent will specify whether the suspension will be

complete or partial, and will provide the State an opportunity to respond and a reasonable amount of time in which to correct the deficiencies specified in the notice. The notice of intent will also specify a proposed date on which the suspension will become effective if the State has not by that time corrected the deficiencies described in the notice of intent. The proposed effective date will be not less than 30 days from the date the notice is received by the State. The notice of intent will also be published in the Federal Register, and the public given an opportunity to comment thereon, if the State does not correct the specified deficiencies within the reasonable time allowed by the notice, or the Administrator withdraws the notice of intent before that time.

(2) If requested by the affected State lead agency within 30 days of receipt of the notice of intent to suspend, an informal consultation between appropriate State and EPA officials will be held to discuss the proposed suspension. In such a case, the Administrator shall not make a final decision on the suspension until after the consultation. The Administrator shall consider all relevant information presented at the consultation, or in any other appropriate manner, in determining whether to suspend the State's authority.

(3) If, after the time specified in the notice of intent, and after any consultation held pursuant to paragraph (b)(2) of this section, the Administrator finds that the State has not corrected, or cannot correct in a reasonable time, the deficiencies specified in the notice of intent, the Administrator may suspend the State's authority to register pesticides under section 24(c) of FIFRA. In such a case, the Administrator will issue a written notice of suspension to the State, specifying the grounds therefor and an effective date for the suspension. If the suspension is merely partial, the notice of suspension will specify the types of registrations which will not be recognized under FIFRA. The notice of suspension will also be published in the Federal Register.

(d) *Termination of suspension.* Suspension of a State's authority will be effective for the period specified in the notice of suspension, or if no period was specified, until such time as the Administrator is satisfied that the State can and will exercise adequate control over its program. At that time, the Administrator will notify the State that the suspension is terminated, or that it will be determined on a specific date. The Administrator will also publish a

notice of the termination of suspension in the Federal Register.

§ 162.156 General requirements.

(a) *Requirements for distribution of use.* (1) Any product whose State registration has been issued in accordance with §§ 162.152 and 162.153 may be distributed and used in that State, subject to the following provisions of the Act and the regulations promulgated thereunder:

(A) Section 12(a)(1) (A) through (E) in accordance with:

(i) Section 2(q)(1) (A) through (G); and

(ii) Section 2(q)(2) (A) through (D);

(B) Section 12(a)(2) (A) through (G) and (I) through (P).

(2) A product or use classified by a State for restricted use under § 162.153(g) may be used only by, or under the direct supervision of, an applicator certified under a plan implemented in that State in accordance with section 4 of FIFRA.

(3) State registrations which are not issued in accordance with § 162.152 (a) and (b) are not authorized by section 24(c) and are not considered valid for any purposes under FIFRA. The Administrator may notify the registering State that a registration is invalid, and may specify the reasons for the registration's invalidity.

(b) *Establishment registration requirements.* No person may produce any pesticide, including any pesticide registered by a State under section 24(c), unless the establishment in which it is produced is registered by the Administrator in accordance with section 7 of FIFRA and 40 CFR Part 167.

(c) *Books and records requirements.* All producers of pesticides, including those producers of pesticides registered by States under section 24(c), must maintain records in accordance with the requirements imposed under section 8 of FIFRA.

EPA Policy Implementing Amendments to Section 24(c) of FIFRA Pending Promulgation of Regulations

Background

On September 30, 1978, the Federal Pesticide Act of 1978, Pub. L. 95-396 amending the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 136 et seq.) [FIFRA] went into effect. The many changes made in FIFRA by Pub. L. 95-396 are described in another notice published in the Federal Register January 19, 1979 (44 FR 4359).

Among the sections of FIFRA which have been substantially modified is Section 24(c) (7 U.S.C. 136v(c)) which authorizes the States to register "additional uses of federally registered pesticides * * * to meet special local needs". In general, the amendments to Section 24(c) broaden State authority to issue

such registrations, while they correspondingly limit EPA's authority to oversee the State registration process. For example, the former requirement that States obtain certification from EPA prior to registering pesticides has been eliminated, and registration authority has been given directly to the States. Also, EPA's former broad authority to disapprove specific State registrations is now subject to certain express procedural and substantive restrictions.

Clearly, these amendments reflect Congress' intent to redistribute the power over special local needs registration, with greater autonomy being given to the States. Nevertheless, EPA retains ultimate authority to ensure that the States act in accord with the purposes of FIFRA and to prevent unreasonable adverse effects on the environment. Implementation of this new relationship will require close cooperation between EPA and the States. (Such cooperation is, in fact, strongly encouraged by Section 24(c) as a requirement placed on the process by which EPA may disapprove State registrations.) This redistribution of authority also necessitates the revision of the "Interim" program established by EPA in 1975 to implement the original version of Section 24(c), including the proposed regulations accompanying the "Interim" program. [40 FR 40438-40545 (September 3, 1975)].

This policy document discusses the changes in State authority made by the amendments; explains how EPA intends to exercise its disapproval authority; and describes registration procedures which EPA believes the State should continue to follow. It also provides basic guidance for States, registrants, and EPA to follow until final regulations required by the amended Section 24(c) are promulgated. More detailed procedural information will be provided to augment this memorandum in a separate Guidance Package which EPA will make available, on request, to interested persons in the near future.

Questions or comments concerning this policy should be addressed, in writing, to Phil Gray (TS-770), U.S. EPA, Operations Division, Office of Pesticide Programs, 401 M Street, S.W., Washington, D.C. 20460.

Elimination of Section 24(c) Certification Program

The most significant change made by these amendments is the elimination of the provision requiring States to obtain certification from EPA prior to registering pesticides for special local needs. This certification process required a determination by EPA that a State's procedures and legal authority for registration would assure compliance with FIFRA and federal regulations thereunder.

States are now directly authorized by Section 24(c)(1) itself to register "additional uses of federally [EPA] registered pesticides * * * to meet special local needs", without prior EPA approval. However, EPA is given the authority to suspend a State's registration power, after consultation with the State, if the State is

unable, or refuses, to exercise "adequate control" over its registration process. Such authority cannot be exercised, though, until EPA has promulgated regulations establishing grounds and procedures for suspension. These regulations will be developed and proposed in the near future. Although no such criteria have yet been developed, it is possible that future regulations could provide for some form of partial suspension where circumstances would not warrant complete suspension.

State Registration Authority

Under the amended Section 24(c), States may issue registrations for the same purposes as they could under the original Section 24(c). These purposes include: (a) use of new formulations of federally registered chemicals; (b) amendment of federal registrations to permit use on additional crops or pests or at additional sites, or to permit use of different application techniques, rates, and equipment; (c) amendment of federal registrations to require special label directions necessary to prevent unreasonable adverse effects or to ensure efficacy under local conditions; or (d) any other purposes consistent with the purposes of FIFRA.

Also as under the original Section 24(c) program, the States are authorized by the amended section to register pesticides only if all of the following circumstances exist: (a) there is a special local need for the pesticide; (b) the pesticide is labeled for use and distribution within the State (as evidenced by the pesticide's container being labeled with or accompanied by directions for use to meet the special local need and a statement identifying the registering State); (c) the State registration is for use of a chemical found in any product registered by EPA; (d) the use sought to be registered has proper clearances, if required, under the Federal Food, Drug and Cosmetic Act; (e) the use sought to be registered has not been previously disapproved, cancelled, or denied registration by EPA; and, (f) the registration is otherwise in accord with FIFRA.

However, despite the above inherent limitations, the States' authority is broader than that granted under the original Section 24(c) and the "Interim" Program. For example, States may now register uses of a chemical for which registration has not been specifically disapproved, denied, or cancelled by EPA, even though other uses of the same chemical have been disapproved, cancelled, or denied registration. In addition, the amendments to Section 24(c) confirm the States' authority to register a pesticide containing an ingredient subject to an intensive review of risks and benefits under 40 CFR 162.11 (i.e., a "Rebuttable Presumption Against Registration").

Disapproval of State Registrations by EPA

In contrast to the almost unlimited authority to disapprove individual State registrations inherent in the original Section 24(c), EPA's disapproval authority under the amended Section 24(c) is subject to specific procedural and substantive limitations. Procedurally, the Administrator of EPA is

now required to inform the State of his intention to disapprove a registration and of the reasons therefor, and to provide the State time to respond, prior to disapproving most registrations. This amendment formalizes a procedure voluntarily used by EPA under the "Interim" program.

Except as provided under Section 24(c)(3), if requested by a State within ten days of its receipt of a notice of intent to disapprove, EPA will consult with the State to determine if the registration should be disapproved. Such consultations will take place, and any disapproval will be made effective, within 90 days of the effective date of the State registration, as was also the practice under the "Interim" program. However, under Section 24(c)(3), the Administrator may disapprove a State registration without prior notice to the State if the registration would result in an imminent hazard to man or the environment, or if the registration lacks necessary tolerances, exemptions, or other clearances under the Federal Food, Drug, and Cosmetic Act, for use involving food or feed. [If a State registration is disapproved because it involves an imminent hazard, EPA may also suspend any similar federal registrations.]

Although not expressly required by the new Section 24(c), the Administrator will also continue to specify a date for termination of the State registration in his decision to disapprove a registration. The Administrator will also, if appropriate, provide for disposition of existing stocks of the pesticide in question.

While the procedures described above are very similar to those previously followed by EPA, the substantive restrictions placed on EPA's disapproval authority significantly limit the scope of that authority. Under Section 24(c)(2), EPA may not disapprove a State registration solely on the grounds of lack of essentiality. In addition, EPA generally may not disapprove an otherwise valid and authorized State registration for which the "composition and use patterns are similar to a federally registered pesticide". Section 24(c)(3) specifies only two express grounds for disapproving such registrations—creation of an "imminent hazard," or if use on food or feed is involved, lack of necessary clearances under the Federal Food, Drug, and Cosmetic Act.

New regulations to be promulgated under Section 24(c) will establish standards for determining similarity and dissimilarity of composition and use patterns. However, for the purpose of implementing Section 24(c)(2) during the period preceeding promulgation of such regulations, EPA will consider a State registered pesticide to have a "similar composition" if it contains the same active ingredients, in essentially the same percentages; is of the same formulation type and category of toxicity; and requires the same precautionary labeling; as an EPA registered pesticide.

In accordance with Congress' clear intent that "similar use pattern" should be interpreted broadly, EPA will consider a pesticide to have a "similar use pattern" if it has substantially the same manner and purposes of application as an EPA registered

pesticide. Additional clarification of this matter was provided by Congress with respect to State registrations that may be considered *not* similar to any federal registration. "State registrations involving changed use patterns—changes from nonfood to food use, from outdoor to indoor use, from terrestrial to aquatic use, and non-domestic to domestic use—will be considered . . . as not involving similar uses . . ." [Conf. Rep. No. 95-1188, 95th Congress, 2d Sess., 51 (1978).]

EPA retains broad authority to disapprove registrations having either a use pattern or a composition which is *not* similar to a federally registered pesticide. State registrations involving such dissimilarities are expressly subject to disapproval on the same grounds as similar registrations—i.e., imminent hazards and lack of necessary clearances under the Federal Food, Drug, and Cosmetic Act—and any other reasonable grounds, which may include: (a) probable creation of unreasonable adverse effects on man or the environment; (b) revocation of the registration by the State; (c) refusal of a State to submit requested information to EPA; or (d) insufficiency of information submitted to support the State registration.

Registrants under Section 24(c) should note that as under the "Interim" program, disapproval of a State registration by the Administrator will not be considered a refusal to register, or a cancellation or suspension of registration, within the meaning of Section 3(c)(6) or Section 6 of FIFRA. Therefore, a registrant of a disapproved State registration will not be entitled to a hearing on such an action under Section 6 of FIFRA.

State Registration Procedures

Underlying the new amendments to Section 24(c) is a basic Congressional intent that the regulation of pesticides should be a *national* program, not an exclusively federal program. These amendments emphasize the EPA and the States are partners in regulating pesticides, and that a concerted federal and State effort to work together, and to exchange information and views, is necessary to properly protect the public health, while still responding to the needs of pesticide users. It is only in an atmosphere of mutual respect and cooperation that these tasks can be effectively performed.

In order to carry out these duties, States should follow minimal procedures, and EPA and the States should routinely forward to each other specific information, as described below. Such information is needed to keep both parties informed of actions taken by the other, so that both parties can properly perform their share of the duties created by this cooperative program. On its part, EPA will also consult with the States whenever discussion or clarification of State actions is appropriate.

Applications for State registration should continue to include the name and address of the applicant and any other person whose name will appear on the pesticide labeling or with the directions for use; the name of the product; a complete copy of the labeling showing all claims made for the product and

directions for its use to meet the special local need; and the complete formula of the product.

In reviewing an application for State registration, the responsible State agency should determine whether there is a "special local need" for the registration. Although the need for such a determination still exists under Section 24(c)(1), Section 24(c)(2)(A) requires a complete revision of the meaning assigned to that term under the "Interim" program. Therefore, during the period preceding promulgation of new regulations, the States will have the responsibility to decide, on a case-by-case basis, whether a "special local need" exists for a State registration. However, since "conditional registration" under Sec. 3 of FIFRA will be available to registrants very soon, EPA expects the States to refuse to register pesticides for which there is a *national*, rather than a genuine *local*, need. By so doing, States will prevent Section 24(c) from being used to circumvent the requirements of Section 3, including requirements on data use and compensation. During this period, EPA will consult with the States and other interested persons to determine the need for adopting a regulation defining "special local need."

In certain cases, before issuing a registration, the State should also determine that the product or use will not cause unreasonable adverse effects on man or the environment when used as directed or in accordance with widespread and commonly recognized practices. This determination should be made before registering: (a) a use of a pesticide with a composition not similar to any EPA registered pesticide; (b) a pesticide use with a use pattern not similar to any EPA registered use for the same pesticide; and (c) a pesticide use for which registration of a different use of the same pesticide has been denied, disapproved, or cancelled by EPA. Such determinations should take into account the effect a restricted use classification, or other terms and conditions of registration, would have on the potential hazard which registration would create. States should base their determinations on data consistent with those parts of the federal registration rule on product hazard [40 CFR 162.8(b)(4)] that are applicable to the type of product or type of use under consideration. (Further details as to data may be found in the Guidance Package referred to earlier in this memorandum.)

States should also impose on applicants for registration, labeling requirements generally consistent with federal labeling requirements (40 CFR 162.10), to prevent the pesticide being considered "misbranded" under section 2(q) and section 12 of FIFRA, since registrations issued under section 24(c) are expressly deemed "registrations under section 3 for all purposes" of FIFRA. Furthermore, under section 24(b), States generally may not permit or require modification or elimination of any labeling approved by EPA in connection with a federal registration. However, State labeling must contain supplemental directions for use to meet special local needs, as well as a statement identifying the State

issuing the registration. Such labeling should be reviewed and approved by the State prior to issuance of State registration.

Similarly, States should continue to require applicants and registrants to comply with federal packaging standards prescribed by the Administrator of EPA under section 25(c)(3) of FIFRA, and federal coloration standards and regulations published under section 23(c)(4) and in 40 CFR 162.13. Compliance with such standards should also be verified by the State prior to issuance of a section 24(c) registration.

Also, since section 24(c) registrations are considered federal registrations, if a State decides to register a pesticide, it should classify the pesticide and its uses consistently with standards promulgated under section 3(d) of FIFRA. Therefore, when registering a product or use identical to or similar in composition and use pattern to, a product or use classified by EPA, States should classify the product or use the same as EPA. When registering a pesticide *use* not similar to any federally classified use of the same product, States should classify the use according to applicable federal standards in 40 CFR 162.11(c). When registering a product whose uses have not yet been classified by EPA, and which is not similar in composition or use patterns to any product classified by EPA, the State need not classify the product until EPA classifies the same or a similar product. Whenever EPA classifies, or reclassifies, a product or use previously registered by the State, the State should thereafter classify the product or use the same as EPA within 90 days of the effective date of the EPA classification.

However, the above is not intended to limit the States' authority to classify a product or use for restricted use, even if EPA has classified the same or a similar product or use for general use, if local conditions require the more restrictive classification. EPA encourages the States to exercise this important prerogative in responding to local circumstances.

As agreed by EPA and officers of the American Association of Pest Control Officials (AAPCO), as representatives of the States, during Congressional conferences on the proposed amendments to FIFRA, States will continue to send written notification of the issuance of each Section 24(c) registration, or amendment or revocation thereof, to the appropriate EPA office within ten days taking any such action. Such prompt communication of State registration decisions is consistent with the amended Section 24(c), and with the cooperative approach to national pesticide regulation which Congress, EPA, and the States have agreed is necessary. EPA needs such information in order to properly react to State registration actions, and in order to maintain a complete list of federal registrations for use by State officials, pesticide users, and the general public.

Notification of registrations or amendments should indicate the effective date of the action, and should be accompanied by a copy of the approved labeling for the registration involved. Notification of revocations should contain a brief explanation of the reasons for

revocation. Within 30 days of issuing a registration or an amendment, the State should also send EPA a copy of the final approved labeling.

Additional Information on Certain Registrations

In cases involving the registration by a State of a use of a pesticide known or likely to be a potential cause of an imminent hazard to man or the environment, EPA may request the State to submit additional information considered by the State in its decision to issue the registration. Submission of such data is necessary in order for EPA to have a factual basis on which to decide whether the State registration would create an imminent hazard or other unreasonable risk which might require disapproval of the registration.

Accordingly, EPA may request a State to submit copies of data used, and the findings made, in connection with the unreasonable adverse effects review done for each State registration of a pesticide use similar to a use disapproved, cancelled, or denied registration by EPA. The same information may also be requested for each registration of a use of a pesticide for which EPA has disapproved, cancelled, or denied registration of a different use of the same pesticide, if the use registered by the State is not similar to any use considered by EPA in the disapproval, cancellation, or denial proceedings for that pesticide. In addition, this information may be requested for any State registration of a use similar to a use considered but allowed by EPA during cancellation or denial proceedings for the product. In this last case, such information would generally be required in situations where the use allowed by EPA was permitted upon specific conditions not imposed by the State.

In the cases described above, submission of the information requested is especially important since the uses registered by the State may involve products already found by EPA to be unreasonably hazardous under some circumstances. In the absence of such data, EPA may be forced to make its determination on the basis of information not as complete as that used by the State, and may thereby disapprove a registration which might not otherwise have been disapproved. In these cases, EPA also encourages the States to consult with EPA *prior* to issuing such registrations, in keeping with the spirit of increased cooperation between EPA and the States, and in order to prevent unnecessary risks to man and the environment.

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Deputy Assistant Administrator for Pesticide Programs.

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